



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,944	09/30/2003	John Hibner	END-814 - 21680.503883	7870

7590 08/24/2007
Philip S. Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
----------	--------------

3736

MAIL DATE	DELIVERY MODE
-----------	---------------

08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,944

Applicant(s)

HIBNER ET AL.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 6/22/2007, amended claim(s) 1, 7, and 8, canceled claim(s) 2, and new claim(s) 10-16 is/are acknowledged. The current rejections of the claim(s) 1 and 3-9 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claim 1 is objected to because of the following informalities: the positive recitation of "and" in line 14 appears to be a typographical and/or grammatical error. Appropriate correction is required.

3. Claim 1 is objected to because of the following informalities: the positive recitation of "and" appears to be missing after "g. means for advancing said flexible rod axially toward the distal end of said needle,". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (US 6,428,486 B2, hereinafter Ritchart) in view of Banik et al. (US 5,601,585, hereinafter Banik).

6. For claims 1, 7, 9, 10, and 15, Ritchart teaches a handheld biopsy instrument (10), comprising:

Art Unit: 3736

- a hollow, biopsy, insertion needle (20) having a tissue piecing distal tip (58) and a distally-disposed, axially-extending, open specimen port (28) disposed proximal of the tissue piecing tip for receiving tissue (as best seen Figures 4, 5-6, 18, 20, and 22);
- an elongated, rotatable, translatable, tissue specimen cutter (22) having a distal end, wherein the distal end of the cutter is slidably received within the biopsy needle (as best seen in Figures 4, 5-6, 18, 20, and 22);
- means for applying a first vacuum (the vacuum source positively recited in column 8 lines 53-64) within the distal end of said needle;
- means for advancing said cutter (44) toward the distal end of said needle;
- means for rotating said cutter (40) as said cutter advances within said needle; and
- a removable specimen receiving tube (26).

7. For claims 3 and 11, Ritchart teaches a handheld biopsy instrument (10), wherein the biopsy insertion needle comprises an upper lumen (23) and a lower lumen (35).

8. For claims 4 and 12, Ritchart teaches a handheld biopsy instrument (10), wherein the distal end of the cutter is received within the upper lumen (as best seen in Figures 5 and 6).

9. For claim 6, Ritchart teaches a handheld biopsy instrument (10), wherein lower lumen communicates with a source of vacuum (column 8 lines 53-64).

10. For claims 8 and 16, Ritchart teaches a handheld biopsy instrument (10), wherein the specimen tube and the cutter are capable of advancing and retracting in unison.

11. Thus for claims 1 and 3-16, Ritchart discloses the claimed handheld biopsy instrument, except for explicitly teaching (a) an elongated flexible push rod slidably received within said lower lumen of said needle and parallel to said cutter, wherein said push rod extends to the distal end of said needle; (b) a means for advancing said flexible push rod axially toward the distal end of said needle; and (c) a means at the distal end of said needle for causing said push rod to turn 180 degrees thereby reversing its direction of movement whereby said push rod end enters said cutter, engages said encapsulated tissue specimen therein, thereby moving said tissue specimen axially toward the proximal end of said cutter, as claimed in claims 1, 5, 9, 10, 13, 14.

12. Banik teaches a handheld biopsy instrument (11), comprising: (a) an elongated flexible push rod (25,52) slidably received within a lower lumen (26) of a needle (10) and parallel to a cutter (22), wherein said push rod extends to the distal end of said needle (column 3 lines 38-47 and column 5 lines 4-59); (b) a means for advancing said flexible push rod axially toward the distal end of said needle (column 3 lines 38-47 and column 5 lines 4-59); and (c) a means at the distal end of said needle for causing said push rod to rotate 180 degrees (column 3 lines 38-47 and column 5 lines 4-59) thereby reversing its direction of rotation wherein said push rod is capable of entering said

Art Unit: 3736

cutter, engaging said encapsulated tissue specimen therein, and moving said tissue specimen axially toward the proximal end of said cutter.

13. As set forth above, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Ritchart and Banik. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components of the handheld biopsy device as taught by Ritchart with the components of the handheld biopsy device as taught by Banik to achieve the predictable results of obtaining biopsy specimens and configuring the biopsy device with a means for manipulating the specimens in order to create space within the device for the next specimen when collecting multiple biopsy specimens.

Response to Arguments

14. Applicant's arguments, see pages 5-8, filed 6/22/2007, with respect to the rejection(s) of claim(s) 1, 3, 4 and 6-8 under 35 USC 102(b) as being anticipated by Ritchart have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Banik, wherein claims 1 and 3-16 are rejected under 35 USC 103(a) as being unpatentable over Ritchart in view of Banik as set forth above.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700